UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

CIVIL ACTION NO. 13-10628

EXERGEN CORPORATION

v.

KAZ USA, INC.

MEMORANDUM AND ORDER ON EXERGEN'S MOTION FOR SUMMARY JUDGMENT ON KAZ'S INEQUITABLE CONDUCT DEFENSE

August 10, 2015

STEARNS, D.J.

Plaintiff Exergen Corporation accuses defendant Kaz USA, Inc., of infringing U.S. Patent Nos. 6,292,685 (the '685 patent) and 7,787,938 (the '938 patent).[1] Kaz asserts, *inter alia*, the defense that the patents-in-suit

[1] The '685 and '938 patents are both entitled "Temporal Artery Temperature Detector" and list Dr. Francesco Pompei as the inventor. The '685 patent was issued on September 18, 2001, and the '938 patent was issued on August 31, 2010. The '938 patent is a continuation of the application that matured into the '685 patent, and the two patents share virtually the same specification. As described in the court's memorandum and order construing the disputed claim terms, the patents disclose methods and apparatuses for detecting the temperature at the forehead over the temporal artery, and for computing an internal body temperature based using the arterial heat balance approach. Of the asserted claims, claim 14 of the '685 patent is representative:

> 14. A method of detecting human body temperature comprising:

are unenforceable because Exergen intentionally withheld material art references during the prosecution before the Patent and Trademark Office (PTO). Exergen moves for summary judgment, contending that Kaz cannot shoulder the heavy evidentiary burden of proving inequitable conduct.[2]

The burden of proof is indeed weighty. "Inequitable conduct is an equitable defense to patent infringement that, if proved, bars enforcement of a patent." *Therasense, Inc. v. Becton, Dickinson & Co.*, 649 F.3d 1276, 1285 (Fed. Cir. 2011). As the Federal Circuit recognized in *Therasense*, the "far-reaching consequence" of this "atomic bomb" remedy made inequitable conduct "a common litigation tactic" that "plagued not only the courts but also the entire patent system." *Id*. at 1288, 1289. Over time, "low standards for meeting the intent requirement" and "a broad view of materiality" have

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> detecting temperature at a forehead through a lateral scan across the temporal artery; and
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> computing an internal body temperature of the body as a function of ambient temperature and sensed surface temperature.

[2] The court has previously issued a memorandum and order on the parties' cross-motions for summary judgment on Kaz's license defense. Kaz's additional motions for summary judgment of non-infringement, no willful infringement, and invalidity because of obviousness are currently pending.

led to "many unintended consequences, among them, increased adjudication cost and complexity, reduced likelihood of settlement, burdened courts, strained PTO resources, increased PTO backlog, and impaired patent quality." *Id.* In *Therasense*, the Court "tighten[ed] the standards for finding both intent and materiality in order to redirect a doctrine that has been overused to the detriment of the public." *Id.* at 1290.

Like other equitable doctrines, "inequitable conduct hinges on basic fairness." *Id*. at 1292. "Because inequitable conduct renders an entire patent (or even a patent family) unenforceable, . . . this doctrine should only be applied in instances where the patentee's misconduct resulted in the unfair benefit of receiving an unwarranted claim." *Id*.

"Intent and materiality are separate requirements" of an inequitable conduct claim. *Id*. at 1290.

> [A]s a general matter, the materiality required to establish inequitable conduct is but-for materiality. When an applicant fails to disclose prior art to the PTO, that prior art is but-for material if the PTO would not have allowed a claim had it been aware of the undisclosed prior art. In making this patentability determination, the court should apply the preponderance of the evidence standard and give claims their broadest reasonable construction.[3]

[3] The Court carved out a narrow exception – affirmative egregious acts, such as the filing of a false affidavit, are material without having to satisfy the but-for test. *Id*. at 1292. Mere non-disclosure of prior art references does not constitute affirmative egregious misconduct. *Id.* at 1295-1293.

Id. at 1291-1292. In addition to materiality, "the accused infringer must prove that the patentee acted with the specific intent to deceive the PTO." *Id.* at 1290.

> A finding that the misrepresentation or omission amounts to gross negligence or negligence under a "should have known" standard does not satisfy this intent requirement. In a case involving nondisclosure of information, clear and convincing evidence must show that the applicant *made a deliberate decision* to withhold a *known* material reference. In other words, the accused infringer must prove by clear and convincing evidence that the applicant knew of the reference, knew that it was material, and made a deliberate decision to withhold it.

Id. (internal quotation marks and citations omitted, emphasis in original). The Court cautioned district courts to refrain from applying a "sliding scale,"

> where a weak showing of intent may be found sufficient based on a strong showing of materiality, and vice versa. Moreover, a district court may not infer intent solely from materiality. Instead, a court must weigh the evidence of intent to deceive independent of its analysis of materiality. Proving that the applicant knew of a reference, should have known of its materiality, and decided not to submit it to the PTO does not prove specific intent to deceive.

Id.

Kaz contends that Exergen, and Dr. Pompei specifically, intentionally omitted several key art references during the prosecution of the patents-in-suit before the PTO that would have defeated patentability. These include Exergen's DermaTemp device, Exergen's § 501(k)

application[4] to seek the Food and Drug Administration (FDA)'s pre-market approval for its TemporalScanner product, the Physicians Reference Handbook on Temperature (co-authored by Dr. Pompei and published by Exergen), and an article in the scientific journal Acta Physiologica Scandinavia by T. K. Bergersen entitled "*A search for arteriovenous anastomoses in human skin using ultrasound Doplar*."[5]

DermaTemp is a series of commercial infrared thermographic skin temperature scanners manufactured by Exergen that was marketed beginning in 1987. According to the operating manual, "[t]hese instruments instantly measure temperature on any surface location of the human body without the need for tissue contact." Dkt. # 84-5 at 3. "The versatility of the products allows for absolute temperature measurement,

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[4] The § 501(k) application seeks approval to market a medical device that is "substantially equivalent" to a pre-existing (and previously approved) device. *See http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/510kClearances/* (accessed August 5, 2015).

[5] Kaz also argues that Exergen committed inequitable conduct by withholding Exergen's U.S. Patent No. 5,012,813 during the prosecution of the '685 patent. However, because "inequitable conduct, while a broader concept than fraud, must be pled with particularity" under Fed. R. Civ. P. 9(b), *Ferguson Beauregard/Logic Controls, Div. of Dover Res., Inc. v. Mega Sys., LLC*, 350 F.3d 1327, 1344 (Fed. Cir. 2003), and Kaz did not plead this theory in its Answer and Counterclaims to Exergen's Third Amended Complaint, *see* Dkt. # 86, this contention is barred.

surface scanning, and comparative methods of temperature differential." *Id.* at 12. The manual disclosed several modes of operation (SCAN, MAX, and MIN), and described numerous clinical applications for the use of the device, including determining the temperature gradient between the forehead and the sole to detect shock, measuring temperatures at different sides of the forehead to determine blood flow anomalies, and monitoring the extracranial carotid complex for early signs of stroke.[6] *Id.* at 3, 15, 20, 22. For purposes of shock detection, the manual indicated that a user may "[a]ssum[e] forehead and abdominal readings [to] correspond to core temperature, and sole and palm readings to shell temperature." *Id.* at 22. Kaz contends that the DermaTemp was material art because it taught taking a person's core temperature by scanning the forehead.[7]

In April of 2001, Exergen filed the § 501(k) application for FDA approval of its TemporalScanner product – Exergen's own temporal artery

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[6] The manual also suggested using the DermaTemp in headache clinics, *id.* at 22, which Kaz argues would also necessitate taking temperature at the forehead.

[7] The manual cautioned, however, that skin temperature could vary with "skin characteristics, wet skin, and environmental influences." *Id.* at 12. In particular, "absolute temperature readings must be interpreted in relation to [ambient temperature], and the practitioner should be careful to protect the patient from drafts or exposure to large cold surfaces, to position the extremities to minimize pooling, and to allow time for the surface temperature to equilibrate to its environment." *Id.*

thermometer. In the application, Exergen compared the TemporalScanner with two predicate devices in a chart – the DermaTemp, and the Braun Thermoscan IRT 3020/3520. With respect to "Technology Used," Exergen identified the "Arterial Heat Balance" approach for all three devices. Dkt. # 86-5 at 6-1. Although the § 501(k) application was not prior art, Kaz asserts that it was material because it characterized the DermaTemp, which taught taking a person's core temperature at the forehead, as also using the same arterial heat balance approach as the patents-in-suit.[8]

Chapter 5 of the Physicians Reference Handbook, published in 1996, provides a "*Tutorial on Arterial Thermometry via Heat Balance at the Ear*." Underwood Decl. Ex. 14. The Tutorial explains that while

[8] Dr. Pompei attested that for manufacturing efficiency, the firmware (software) of the DermaTemp was the same as that for its ear thermometer, which did use the arterial heat balance approach. The DermaTemp, however, was programmed with a k-factor of 1 and therefore did not compensate for ambient heat loss. This explanation is consistent with some of the disclosures within the § 501(k) application. With respect to "Display modes," the § 501(k) application noted that while the TemporalScanner's "[d]isplayed temperature is the actual temperature of the temporal artery plus a mathematical adjustment to approximate the familiar rectal range," the DermaTemp's "[d]isplayed temperature is the actual temperature of the surface of the skin at the point of measurement." *Id*. at 6-2. The application also noted that "[t]he temperature displayed by the [DermaTemp] is the temperature of the skin at any surface of the body. The conversion to a familiar range by the [DermaTemp] is not made, although the firmware would permit such a conversion." *Id*. at 6-3.

temperature measured at the tympanic membrane deep within the ear correlates to the pulmonary artery temperature and thus the core temperature of a person, a measurement taken at the outer ear canal (a more convenient target) is subject to variation as a result of ambient cooling and heat loss. The loss, however, can be computed as a function of the ambient and ear canal temperatures using a series of equations. The taking of the ear canal temperature adjusted by the arterial heat loss compensation can lead to an accurate measurement of the core temperature. The significance of the Physicians Reference Handbook, according to Kaz, is that it disclosed the arterial heat balance equations in the exact form that was included in the patents-in-suit.[9]

The Bergensen study, published in 1993, reported on the search for arteriovenous anastomoses (AVAs) in skin regions of the head and the thorax using Doplar ultrasound. AVAs are "direct links between arterioles and venules. Their structural characteristics include a thick muscular wall and usually a very rich nerve supply. The functional significance of the AVAs is their great capacity to adjust blood flow through the skin. They thus play a central role in temperature regulation." Sternberg Decl. Ex. S

[9] The equations of the Physicians Reference Handbook were not new, but were equivalent to equations disclosed in other prior art patents, after some algebraic manipulation.

at 195. The study reported that its "results do not indicate the presence of AVAs in the skin of the forehead." *Id.* at 200. Kaz opines that the Bergensen study was material because it revealed the relatively constant blood flow of the temporal artery, a feature that made the site particularly useful for temperature taking. Moreover, it demonstrates that Dr. Pompei did not discover this useful feature of the temporal artery.

Exergen contends that, whatever the materiality of these four references, Kaz's evidence fails to establish that "the specific intent to deceive [is] the single most reasonable inference able to be drawn from the evidence." *Therasense*, 649 F.3d at 1290. Kaz's evidence establishes that Dr. Pompei was aware of these four references, and that he worked with his patent attorney in selecting the references to be submitted to the PTO during prosecution. Exergen, for its part, dismisses Kaz's evidence as precisely what the court in *Therasense* warned as failing to demonstrate a deceptive intent – "[p]roving that the applicant knew of a reference, should have known of its materiality, and decided not to submit it to the PTO does not prove specific intent to deceive." *Id.* Moreover, Exergen asserts that deceptive intent cannot be the "single most reasonable inference to be drawn from the evidence," because the factfinder could readily conclude, as Dr. Pompei

attested, that he did not include the contested references because of a good faith belief that they were not material.

Kaz protests that Exergen seeks to impose an overly stringent standard at summary judgment. Because Exergen is the moving party and the court must draw all reasonable inferences in favor of the non-movant, Kaz maintains that the summary judgment standard requires Exergen to demonstrate that "no reasonable jury (or no reasonable court, acting as the factfinder) could find that inequitable conduct had occurred." Opp'n at 1. Kaz relies on *Ohio Willow Wood Co. v. Alps South, LLC*, 735 F.3d 1333 (Fed. Cir. 2013) for the proposition that a claim of equitable conduct survives summary judgment so long as "a reasonable jury *could* conclude that Dr. Pompei acted with deceptive intent." Opp'n at 9 (emphasis added). *Ohio Willow*, however, does not extend as far as Kaz would stretch it. *Ohio Willow* reaffirms that

> deceptive intent must be the single most reasonable inference drawn from the evidence. The inference cannot be based on gross negligence and when there are multiple reasonable inferences that may be drawn, intent to deceive cannot be found. Additionally, because the burden of proof is on the party alleging inequitable conduct, the patentee need not offer a good faith explanation for its alleged misconduct unless a threshold level of deceptive intent has been demonstrated.

Ohio Willow, 735 F.3d at 1351 (internal quotation marks and citations omitted). Consistent with this understanding, the Court in *Ohio Willow*

reversed the denial of summary judgment of no inequitable conduct, not because deceptive intent was one of the possible inferences, but because "the collective weight of th[e] evidence supports our conclusion that the evidence would support a finding of intent that is the *single most reasonable inference* to be drawn from the evidence at this stage of the proceedings." *Id.* (emphasis added).

Evaluating the evidence of intent as an issue independent of materiality, the court agrees with Exergen that deceptive intent is not the "single most reasonable inference" to be drawn from Kaz's evidence. Kaz argues that "[s]ince Dr. Pompei is the one who chooses (with his attorney) which references to submit, it follows that he necessarily made a deliberate decision to withhold the [references,] of which he quite was aware and whose materiality was clear." Opp'n at 8 (emphasis in original). The Federal Circuit has emphatically rejected this very contention: "A court can no[t] infer intent to deceive from non-disclosure of a reference solely because that reference was known and material." *1st Media, LLC v. Elec. Arts, Inc.*, 694 F.3d 1367, 1372-1373 (Fed. Cir. 2012). Because Kaz has not adduced competent evidence to establish the intent element of its inequitable conduct claim, the claim is not viable as a matter of law and must be dismissed.

ORDER

For the foregoing reasons, Exergen's motion for summary judgment on the inequitable conduct defense is ALLOWED.

SO ORDERED.

/s/ Richard G. Stearns

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UNITED STATES DISTRICT JUDGE